

MEMORANDUM OF UNDERSTANDING
between the

NATIONAL CANCER INSTITUTE
and the

FOOD AND DRUG ADMINISTRATION
on

FIREBIRD

I. Purpose

The purpose of this Memorandum of Understanding (MOU) is to establish a formal collaboration between the U.S. Department of Health and Human Services, Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute (NCI) to develop and implement the Federal Investigator Registry of Biomedical Information Research Data (FIREBIRD), which will enable clinical investigators, NCI, FDA, and industry entities sponsoring clinical trials of investigational drugs ("Sponsors of Drugs and Biologics" or "Sponsors") to manage clinical investigator information electronically in a fully secure manner. FIREBIRD is one of several modules under development as part of an NCI effort in its Center for Bioinformatics (NCICB) to facilitate the exchange of clinical research information between NCI and FDA. To accomplish this objective, NCICB will make use of the cancer Biomedical Informatics Grid (caBIG™), which is a common infrastructure for sharing data, tools, and other resources among all entities engaged in cancer research. FIREBIRD will adhere to the caBIG™ principles of open source, open access, open development, and federation and will be compatible with caBIG™ technical standards. Upon the successful implementation of FIREBIRD, FDA intends to encourage Sponsors of Drugs and Biologics to make official submissions and amendments directly to FIREBIRD and to provide appropriate assistance to such users, which may include the issuance of guidance regarding FIREBIRD.

II. Background

The FDA/NCI Interagency Oncology Task Force (IOTF) was established in 2003 to enhance the efficiency of clinical research and the scientific evaluation of new cancer medications and diagnostics. The FDA and NCI both have interests in expediting the development of new drugs. One of the central goals of the IOTF is to implement an electronic drug application submission system that will help reduce the delays, errors, and costs associated with drug development. Such a system is expected to speed the discovery and delivery of new therapies.

FIREBIRD, the first module of such a system, is envisioned as a common electronic infrastructure that will help accelerate and streamline interactions between sponsors, including NCI, and FDA by facilitating the exchange of clinical investigator information required by FDA to be submitted on

Form FDA - 1572. Once implemented, FIREBIRD is intended to enable sponsors, including NCI, and FDA to manage clinical investigator information electronically in a fully secure manner. This MOU relates solely to FIREBIRD. NCI and FDA will work together to develop subsequent MOUs (or addenda to this MOU) related to other modules of an electronic drug application submission system.

III. Substance of Agreement; Responsibilities of NCI and FDA

This MOU addresses activities related to the development and implementation of FIREBIRD. Information in FIREBIRD will fall into two categories, which, for the purposes of this MOU are referred to as "FDA records" and "non FDA records." "FDA records" refers to any information entered into FIREBIRD by or on behalf of FDA, as well as any information, regardless of who enters it into FIREBIRD, once it is electronically submitted to FDA. In order for any information entered into FIREBIRD by a sponsor, including NCI, or a clinical investigator to become an "FDA record," the system will require the submitter, whether sponsor or clinical investigator, to take an affirmative step acknowledging the fact that the data are now accessible by the FDA. This will be considered a submission to FDA. Once so submitted to FDA, the information becomes available to the FDA and becomes an FDA record. Non FDA records are any information not entered into FIREBIRD by or on behalf of FDA, as well as information entered into FIREBIRD by a sponsor or clinical investigator prior to taking the affirmative step that constitutes submission to FDA.

FDA and NCI will establish a Change Management Board, comprised of representatives of both agencies, to discuss FIREBIRD's technical requirements, and to discuss and decide on changes or enhancements to the technical capabilities of FIREBIRD.

Development of FIREBIRD will occur in four phases: (1) development and testing (2) operational pilot testing (3) production deployment; and (4) actual production. During Phases 1, 2, and 3 of the project, FDA will transfer certain existing FDA information related to clinical investigators to NCI for the sole purpose of preparing such records for entry into FIREBIRD. In order to get FIREBIRD established, during Phases 1, 2 and 3, both FDA and NCI will have access to these FDA records and NCI's access to FDA records during this period is subject to the restrictions enumerated in III.A. of this agreement. After the conclusion of Phase 3, NCI will not seek to access records in the FDA records component of FIREBIRD. During the first 6 months of phase 4 of FIREBIRD, the system will limit access to FDA records solely to FDA and the contractor functioning as NCI's database administrator for FIREBIRD, and the contractor will be bound by the same restrictions set forth in III.A. of this agreement. Thereafter only FDA will have access to "FDA records." Information entered into FIREBIRD by or on behalf of FDA will reside only in the "FDA records" component. FIREBIRD will also facilitate access to limited data that will be published by the FDA to the public. Notwithstanding all of the foregoing, however, it is understood that NCI may be required to access records on its server if so required by law.

The specific responsibilities of the two parties to this MOU are as follows:

A. *The National Cancer Institute (NCI)*

- NCI will lead the development of FIREBIRD and provide for the maintenance of all hardware, software, and databases.
- NCI will design FIREBIRD to meet the requirements identified for the implementation of FIREBIRD. Changes or enhancements to the technical capabilities of FIREBIRD will only be made upon the approval of the Change Management Board.
- NCI will ensure that the data collected, stored, and exchanged through FIREBIRD meet applicable FDA requirements set forth in 21 CFR Part 11.
- NCI will not seek to access to any FDA record once the record has been submitted to FDA during phase 4, except as already permitted in accordance with FDA Privacy Act System Notice 09-10-0010 (Bioresearch Monitoring Information System, HHS/FDA (BIMO) or the FDA disclosure regulations set forth in 21 CFR Part 20 or otherwise required by law. However, the system may be designed to permit sponsors, including NCI, or a clinical investigator to create a mirror or duplicate of the record in the non FDA records component of FIREBIRD. NCI will protect all FDA records from disclosure in accordance with applicable laws and regulations.
- For information transferred by FDA to NCI for preparation and entry into FIREBIRD during Phases 1, 2 and 3, NCI agrees that, except as necessary for facilitating the information's entry into FIREBIRD, NCI will not use or disclose such information outside the Department of Health and Human Services without FDA's express written permission, except to the extent required by law. Further, before giving its contractor access to any information transferred by FDA to NCI for preparation and entry into FIREBIRD, NCI will procure written agreement from its contractor not to further use or disclose such information, except to the extent required by law.
- If for any reason NCI plans to discontinue the maintenance of FIREBIRD, NCI will give FDA 60 days' advanced notice of this decision and transfer the system, software, and FDA records, as well as documentation, procedures and instructions concerning the normal and emergency operation of the FIREBIRD software, to FDA, or another party mutually agreed upon and in compliance with all applicable laws and regulations, in a timely fashion.

B. *The Food and Drug Administration (FDA)*

- FDA will inform NCI of all necessary server security requirements.
- FDA will work with NCI to ensure that FIREBIRD contains all necessary server security requirements.
- FDA will develop a transition plan to migrate FDA's current clinical investigator data to the FIREBIRD system, which is intended to eventually become FDA's repository for storing and obtaining access to clinical investigator data required under 21 CFR 312.
- FDA staff will enter into FIREBIRD relevant clinical investigator-related data submitted to FDA as well as other data generated by FDA (e.g., completed inspection dates and disqualification determinations).

- FDA will encourage sponsors and clinical investigators to submit appropriate information to FDA using FIREBIRD.

IV. Funds

None of the activities outlined above currently requires the exchange of funds between NCI and FDA. In the event that the transfer of funds is deemed to be required in the future, the parties may enter into an interagency agreement pursuant to Section 601 of the Economy Act of 1932, as amended (31 U.S.C. 1535).

V. Information-Sharing, Reports, and Notices

FDA shall determine, in compliance with applicable law, whether to disclose information in the FDA records component of FIREBIRD. Proprietary and/or nonpublic information submitted by sponsors, including NCI, or clinical investigators, to the "Non FDA records" component of FIREBIRD will not be publicly disclosed by NCI, unless such disclosure is governed by appropriate confidentially disclosure agreements, or to the extent such disclosure is required by law. If NCI receives a request, order or demand for FDA records, including a request under the Freedom of Information Act, 5 U.S.C. 552, NCI will refer that request to FDA for response.

VI. Liaison Officers

Randy Levin
Director for Health and Regulatory Data Standards
Food and Drug Administration
Tel: 301-827-7784

NCI Project Officer
Peter Covitz
Chief Operating Officer
Center for Bioinformatics
National Cancer Institute
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VII. Duration of MOU; Modifications; Termination

This MOU shall become effective on the date of signature by the parties and shall remain in effect for two (2) years unless modified by the mutual agreement of the parties upon sixty (60) days' notice in writing, or until such time as the system and software have been transferred to the FDA or a mutually agreed upon third party. If either party wishes to terminate this MOU, it may do so by giving 60 days' advance notice of this decision to the other party and must ensure that records belonging to the other party are transferred to the other party in a timely fashion.

VIII. SIGNATURES OF RESPONSIBLE PARTIES

We, the undersigned, agree to abide by the terms and conditions of this MOU.

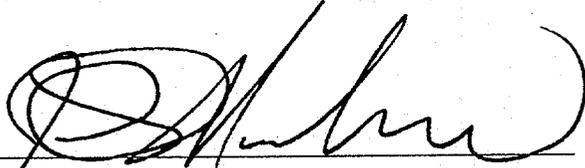
APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION



Janet Woodcock, M.D.
Deputy Commissioner for Operations
and Chief Operating Officer (COO)
U.S. Food and Drug Administration

Date 8/10/06

APPROVED AND ACCEPTED FOR THE NATIONAL CANCER INSTITUTE



John E. Niederhuber, M.D.
Acting Director, NCI and
Deputy Director for Translational
and Clinical Sciences
National Cancer Institute

Date August 10, 2006